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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,732	09/06/2006	Shigeki Kawarabata	10873.1912USWO	8677

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,732	KAWARABATA ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/6/06, 2/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim*** rejected under 35 U.S.C. 102(b) as being anticipated by JP 2000-299 to Araki et al.

In the specification and figures, Araki discloses the apparatus as claimed by applicant. With regard to claim 1, Araki discloses an extracorporeal blood circulating apparatus comprising a closed reservoir 3 with a blood storage chamber 16 and a pressure control chamber 17 within a housing 3 (see FIG 1 and accompanying text). The apparatus further comprises an adjusting liquid tank (which may comprise a syringe or bellows, see paragraph 0031), a blood pump 6 connected to the storage chamber 3, blood inflow port 3b, blood outflow port 3a, and an adjusting port 3c, with the blood pump connected to the outflow port 3a and liquid storage tank and controller connected to the adjusting port (see FIGS 1-2 and accompanying text). Araki further discloses that the venous reservoir is partitioned by a flexible septum 18 to separate the blood

chamber from the volume adjusting chamber. The liquid adjusting tank and adjusting port are connected by a conduit member 20a, 21a, or 22a that are connected to members that can adjust a flowing amount, thereby meeting the limitations of the claim (see paragraphs 0031, 0032).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-299 to Araki et al.

In the specification and figures, Araki discloses the apparatus substantially as claimed by Applicant.

With regard to claim 4, Araki does not specifically disclose a measuring portion for measuring the amount of adjusting liquid that is stored within the adjusting tank. However, Araki discloses that in some embodiments, the pressure control chamber may comprise a capacity detection means that measures the amount of fluid in the pressure control chamber. From that value, one may calculate the amount of fluid within the storage tank, suggesting the limitations of the claims.

With regard to claim 7, Araki fails to disclose an auxiliary venous reservoir that has an outflow port connecting it to the main venous reservoir. It has been held that

absent the showing of a new and unexpected result, the mere duplication of the working parts of a claimed apparatus is not patentable over the prior art. See MPEP §2144.04(VI)(B). In the instant case, Applicant has not produced evidence of a new and unexpected result from the provision of a second venous reservoir. Accordingly, it is the position of the Examiner that the auxiliary venous reservoir is unpatentable over the prior art.

With regard to claim 6, it is the position of the Examiner that the fine-adjusting port disclosed by Applicant is a duplication of the adjusting port disclosed by Araki. Araki discloses that the amount of fluid in the pressure control chamber is closely controlled. Such a disclosure indicates to the Examiner that it may be controlled by a series of fine adjustments. It has been held that absent the showing of a new and unexpected result, the mere duplication of the working parts of a claimed apparatus is not patentable over the prior art. See MPEP §2144.04(VI)(B). In the instant case, Applicant has not produced evidence of a new and unexpected result from the provision of a second adjustment port, and it is the position of the Examiner that the apparatus disclosed by Araki is capable of fine adjustments without a second port. Accordingly, it is the position of the Examiner that the provision of a second pressure regulating port is unpatentable over the prior art.

6. Claims 2, 3, 5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-299 to Araki et al in view of US 4,573,992 to Marx.

In the specification and figures, Araki discloses the apparatus substantially as claimed by Applicant.

With regard to claims 2 and 3, Araki fails to disclose that the conduit member is made of a flexible tube with a channel adjusting portion. Marx discloses an apparatus for receiving and reinfusing blood comprising hose portions that may be closed off by deforming clamps in order to regulate the pressure therethrough (see column 7, lines 53-67). It would have been obvious to one having ordinary skill in the art at the time of invention to form the conduits disclosed by Araki of a flexible material and provide the conduits with clamps, as disclosed by Marx, in order to regulate the fluid pressure or suction therethrough, as taught by Marx.

With regard to claims 5, 9, and 10, Araki fails to disclose a blockage avoiding channel within the blood storage chamber. However, Marx discloses a space 16 between outer container 11 and flexible wall 12 that provides communication to the pressure connection port (see FIG 1 and column 8). The space allows for free communication between the chamber and the port such that the flexible member does not occlude the port. Furthermore, Marx illustrates that blood inlet and outlet ports (2 and 3, respectively), are located on an area of the container 11 that bulges outward from the cylindrical walls at the top and bottom of the container. Such a bulge prevents the inlet and outlet from occlusion by flexible container 12. Since all of the elements are known in the art, it is the position of the Examiner that one having ordinary skill in the art could have combined the known elements (the bulged channels disclosed by Marx into the venous reservoir disclosed by Araki) by known methods, yielding only the

predictable result of a venous reservoir with a rigid chamber and a flexible element whereby the flexible element is prevented from blocking ports.

With regard to claims 11 and 12, the cited prior art fails to disclose an air vent port and a separator membrane. However, Marx discloses that port 17 may provide two-way flow to the pressure adjusting chamber, and may be open to the atmosphere with some membrane between the port at the atmosphere (see FIG 1). Marx discloses a single port that performs all the functions of the two ports claimed by Applicant. As such, it is the position of the Examiner that the air vent port claimed by Applicant is a duplication of the multipurpose port disclosed by Marx. Absent a showing of new and unexpected results, it is the position of the Examiner that separating the functions of port 17 disclosed by Marx into two separate ports is unpatentable over the prior art.

With regard to claim 13, Araki discloses that in some embodiments, the blood chamber may comprise a capacity detection means that measures pressure in the blood chamber, which is fluidly connected to the blockade reduction bulges.

With regard to claim 14, Marx illustrates that the bulges at the ends of the rigid container 11 may take the form of grooves when viewed from the interior of container 11.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-299 to Araki et al in view of US 5,683,357 to Magram.

In the specification and figures, the cited prior art discloses the apparatus substantially as claimed by Applicant.

With regard to claim 8, the cited prior art fails to disclose a supporting unit holding the adjusting liquid tank in order to provide height adjustability. It is well known in the art of fluid handling that the height of a fluid container relative to its connected destination affects the fluid pressure at each end. Height adjustments provide a gradual way to adjust fluid pressures in a fluid circuit, as taught by Magram (see, generally, columns 7-8). As such, providing supports such as IV poles, that allow fluid container height adjustments, are well-known in the art (see Magram column 8, lines 30-45). As such, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the apparatus disclosed by Araki with a supporting unit such as an IV pole as disclosed by Magram, in order to adjust fluid pressure between fluid receptacles, as taught by Magram.

8. Claims 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-299 to Araki et al in view of US 4,573,992 to Marx, further in view of US 5,683,357 to Magram.

With regard to claims 15 and 17, the cited prior art suggests the claimed apparatus. Araki discloses the steps of connecting the apparatus to a patient, with adjusting liquid in the circuit. Marx discloses the step of using a clamp to regulate the amount of fluid that flows into the regulating chamber, and Magram discloses the steps of adjusting a height of a fluid supply bag to control fluid pressure in a circuit. Taken together, the references reasonably suggest the control of an extracorporeal blood circuit with a flexible-septum reservoir and fluid height adjustments.

With regard to claim 16 and 18, Araki fails to disclose that the conduit member is made of a flexible tube with a channel adjusting portion. Marx discloses an apparatus for receiving and reinfusing blood comprising hose portions that may be closed off by deforming clamps in order to regulate the pressure therethrough (see column 7, lines 53-67). It would have been obvious to one having ordinary skill in the art at the time of invention to form the conduits disclosed by Araki of a flexible material and provide the conduits with clamps, as disclosed by Marx, in order to regulate the fluid pressure or suction therethrough, as taught by Marx.

With regard to claim 20, it is the position of the Examiner that the fine-adjusting port disclosed by Applicant is a duplication of the adjusting port disclosed by Araki. Araki discloses that the amount of fluid in the pressure control chamber is closely controlled. Such a disclosure indicates to the Examiner that it may be controlled by a series of fine adjustments. n the instant case, Applicant has not produced evidence of a new and unexpected result from the provision of a second adjustment port, and it is the position of the Examiner that the apparatus disclosed by Araki is capable of fine adjustments without a second port. Accordingly, it is the position of the Examiner that the provision of a second pressure regulating port is unpatentable over the prior art.

Allowable Subject Matter

9. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: The cited prior art generally suggests the steps of connecting the claimed apparatus to the patient and manipulating fluid pressure with reservoir height adjustments, but fails to disclose or suggest the steps of maintaining a specific cross-sectional area of a fluid vessel, decreasing the discharging amount, and terminating the process.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 3,907,504 Hammond et al

i. Flexible blood reservoir

b. US 4,772,256 Lane et al

ii. Autotransfusion of blood with flexible reservoir

c. US 4,976,707 Bodicky et al

iii. Fluid collection and infusion apparatus

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
9 April 2009